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10/552,552	10/07/2005	Marc De Block	58764.000049	2007

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EXAMINER	
KUMAR, VINOD	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
10/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,552	DE BLOCK, MARC	
	Examiner	Art Unit	
	VINOD KUMAR	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11-16 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11-16 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Objections and Rejections

1. Applicant's response filed 8/26/2009 is entered

2. Claims 1-8, 10 and 17-21 are cancelled. Claims 22-24 are newly added claims. Newly added claims 22-24 fall within the scope of the elected invention. Accordingly, claims 9, 11-16 and newly added claims 22-24 are examined on merits in the present Office action.

3. Objections to claims 9 and 16 have been withdrawn in light of claim amendment filed in the paper of 8/26/2009.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Rejection of claims 9 and 11-16 under 35 U.S.C. 112, 1st paragraph has been withdrawn in light of claim amendment and persuasive arguments filed in the paper of 8/26/2009. Rejection of claim 10 under 35 U.S.C. 112, 1st paragraph has been withdrawn in light of cancellation of claim 10 filed in the paper of 8/26/2009.

6. Rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (WIPO, WO 03/000898, Published January 3, 2003, Applicant's IDS), and further in view of Wesley et al. (The Plant Journal, 27:581-590, 2001) and Panda et al. (Developmental Cell, 3:51-61, July 2002; Applicant's IDS) is withdrawn in light of cancellation of claim 10 filed in the paper of 8/26/2009.

Claim Rejections - 35 USC § 103

7. Claims 9 and 11-16 remain, and newly added claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (WIPO, WO 03/000898, Published

January 3, 2003, Applicant's IDS), and further in view of Wesley et al. (The Plant Journal, 27:581-590, 2001) and Panda et al. (Developmental Cell, 3:51-61, July 2002; Applicant's IDS) for the reasons of record as stated for claims 9, 10 (now cancelled), and 11-16 in the Office action mailed 4/28/2009.

Chang et al. teach a transgenic plant and a method of making a transgenic plant comprising transformation of said plant with a DNA expression cassette comprising a plant-expressible promoter operably linked to a ParG (poly(ADP-ribose) glycohydrolase) nucleotide sequence as defined in SEQ ID NO: 550 which has high sequence identity (83.9%) to instant SEQ ID NO: 3, and wherein said nucleotide sequence is in antisense orientation relative to the promoter, and transcribes to yield a ParG molecule which inhibits the expression of endogenous ParG expression in the transformed plant. The reference also teaches down-regulation of endogenous ParG gene expression in a plant, comprising transformation of said plant with a DNA construct comprising sense and/or antisense sequences of SEQ ID NO: 550 to down-regulate or inhibit endogenous ParG gene expression in said plant. The reference teaches seeds of the transformed plant and a method of transferring said DNA expression cassette to a non-transgenic plant through crossing between said transgenic plant and a plant lacking said DNA expression cassette. The reference also teaches transgenic *Arabidopsis* or *Brassica* plants comprising said DNA expression cassette. The reference also teaches that said expression cassette further comprises a 3' end region involved in transcription termination and polyadenylation. The reference also teaches that said transgenic plants are produced by transforming plant (*Arabidopsis* or *Brassica* or tobacco) cells with said expression cassette (designed to produce inhibitory RNA molecule) and subsequent regeneration and identification of the transgenic plant with an expected

phenotype (e.g. disease resistance etc.). See in particular, SEQ ID NO: 550; claims 27-57, 57-58, 63-67; page 34, lines 23-29; pages 53, 98-99, 100-108.

Chang et al. do not teach using RNAi (double stranded inhibitory RNA) based method of down-regulating endogenous plant gene expression.

Wesley et al. teach hpRNA (hairpin RNA) (same as RNAi; double stranded inhibitory RNA) based method of gene silencing in plants. The reference also teaches that double-stranded inhibitory RNA based method of silencing endogenous plant genes is highly efficient compared to other methods of silencing or suppressing plant gene expression. The reference further teaches that about 90-100% independent transgenic plants exhibit gene silencing using RNAi based method. The reference also teaches a method of making DNA constructs which produce double stranded inhibitory RNA upon expression in a plant. See in particular, page 581, abstract; page 582, figure 1; page 585, figure 3; page 586, figure 4; page 587, table 1, figure 5; page 588, figure 6; pages 588-589, materials and methods.

Panda et al. teach ParG (poly(ADP-ribose) glycohydrolase) function by isolating *Arabidopsis* mutants disrupted in ParG expression. The mutants grew normally under light stress as shown by *tej* mutation which acted independently of light quality and quantity. The reference also teaches restoring wild-type function in said mutants by complementing with a wild-type ParG using *Agrobacterium* mediated plant transformation method. See in particular, 51, abstract; pages 53-58, figures 1-6; pages 59-60, materials and methods.

At the time the invention was made, it would have been prima facie obvious, and within the scope of an ordinary skill in the art to modify Chang et al. sense, antisense or cosuppression constructs by designing ParG RNAi (double stranded inhibitory RNA) construct using any method of designing RNAi construct including the one taught by Wesley

et al. to suppress the endogenous ParG gene expression with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to do so because Wesely et al. assert that double-stranded inhibitory RNA based method of silencing endogenous plant genes is highly efficient compared to other methods of silencing or suppressing plant gene expression.

Given Panda et al. clearly teach that disrupting ParG gene expression in a plant resulted in the ability of the plant to grow independent of light quality and light intensity as discussed above, it would have been obvious and within the scope of an ordinary skill in the art to inhibit endogenous plant ParG gene expression by transforming a plant with an RNAi inhibitory construct as discussed above, to produce transgenic plants exhibiting tolerance to light quality and light intensity with a reasonable expectation of success. This would imply that said transgenic plants would have also exhibited tolerance to high light stress.

Obviously seeds would have also been produced for the purpose of propagation.

8. **Applicant's arguments and response from the examiner:**

Applicant traverses the rejection in the paper filed 8/26/2009.

Applicant while admitting that Chang et al. provide methods of suppressing gene activity, however, argues that Chang et al. do not teach suppressing the gene activity using RNAi gene suppression technology. Applicant also alleges that Chang et al. SEQ ID NO: 550 is not identical to instant SEQ ID NO: 3. Applicant further alleges that instant SEQ ID NO: 3 is 1647 nucleotides in length, whereas SEQ ID NO: 550 of Chang et al. is 2994 nucleotides in length (response, page 9, lines 4-15).

Applicant's arguments are fully considered but are deemed to be unpersuasive.

It is maintained that at the time the invention was made, it would have been prima facie obvious, and within the scope of an ordinary skill in the art to modify Chang et al. sense, antisense or cosuppression constructs by designing ParG RNAi (double stranded inhibitory RNA) construct using any method of designing RNAi construct that were well known in the art, including the one taught by Wesley et al. to suppress the endogenous ParG gene expression in a plant with a reasonable expectation of success. One of ordinary skill in the art would also have been motivated to employ double stranded RNAi based method of gene silencing because Wesely et al. clearly teach that double-stranded inhibitory RNA is highly efficient (90% to 100% efficiency) method of silencing endogenous plant genes compared to sense, antisense or co-suppression based methods. It is therefore, maintained that it would have been obvious and within the scope of an ordinary skill in the art to have been motivated in using a double strand RNAi based method of down-regulating the expression of an endogenous plant gene (e.g. ParG in the instant case) as an obvious design choice to arrive at the claimed invention with a reasonable expectation of success.

In response to Applicant's argument that instant SEQ ID NO: 3 and SEQ ID NO: 550 of Chang et al. are not identical, it is noted that instant claims are not restricted to instant SEQ ID NO: 3. Rather, claims are also directed to (a) any 163 consecutive nucleotides of instant SEQ ID NO: 3, or (b) nucleotides from positions 973 to 1135 of instant SEQ ID NO: 3. Contrary to Applicant's allegations, Chang et al. SEQ ID NO: 550 does comprises both (a) and (b) as shown below in the sequence comparison:

Qy: instant SEQ ID NO: 3; Db: Chang et al. SEQ ID NO: 550.

```
Qy          1 ATGGAGAATCCGCGAAGATCTTAACTCAATTCTTCCGTACCTTCCACTTGTAATTCGTTCG  60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 ATGGAGAATCGCGAAGATCTTAACTCAATTCTTCCGTACCTTCCACTTGTAATTCGTTCG  60

Qy         61 TCGTCGCTGTATTGGCCGCCGCGTGTGGTGGAGGCGTTAAAGGCAATGTCTGAAGGACCA 120
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Qy       1141 ATATTCATGGATGAAGGAGATAATGAAATTCAGCTTGTCCGAAACGGCAGAGATTCTGGT 1200
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1099 ATATTCATGGATGAAGGAGATAATGAAATTCAGCTTGTCCGAAACGGCAGAGATTCTGGT 1158

Qy       1201 CTTCTGCGTACAGAAACTACTGCGTCACACCGAACTCCACTAAATGATGTTGAGATGAAT 1260
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1159 CTTCTGCGTACAGAAACTACTGCGTCACACCGAACTCCACTAAATGATGTTGAGATGAAT 1218

Qy       1261 AGACAAAAGCCTGCTAACAATCTTATCAGAGATTTTTATGTGGAAGCAGTTGATAACGAG 1320
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1219 AGACAAAAGCCTGCTAACAATCTTATCAGAGATTTTTATGTGGAAGCAGTTGATAACGAG 1278

Qy       1321 GATCATGAAGATGATGGTGTCGCGACAGGGAATTGGGGATGTGGTGTTTTTGGAGGAGAC 1380
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1279 GATCATGAAGATGATGGTGTCGCGACAGGGAATTGGGGATGTGGTGTTTTTGGAGGAGAC 1338

Qy       1381 CCAGAGCTAAAGGCTACGATACAATGGCTTGCTGCTTCCCAGACTCGAAGACCATTTATA 1440
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1339 CCAGAGCTAAAGGCTACGATACAATGGCTTGCTGCTTCCCAGACTCGAAGACCATTTATA 1398

Qy       1441 TCATATTACACCTTTGGAGTAGAGGCACTCCGAAACCTAGATCAGGT 1487
             |||||||||||||||||||||||||||||||||||||||||||||||
Db       1399 TCATATTACACCTTTGGAGTAGAGGCACTCCGAAACCTAGATCAGCT 1445
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Additionally, it is noted that Chang et al. SEQ ID NO: 550 also encodes poly-(ADP-ribose)-glycohydrolase (ParG) protein.

Furthermore, Panda et al. also teach a nucleotide sequence having 100% identity to instant SEQ ID NO: 3, and which encodes poly-(ADP-ribose)-glycohydrolase (ParG) protein which has 100% identity to instant SEQ ID NO: 1. Panda et al. cite GenBank Accession No. AF394690 (see page 61, last line of right column), wherein the complete nucleotide sequence and its encoded poly-(ADP-ribose)-glycohydrolase (ParG) protein is taught.

Applicant further argues that Panda et al. provide no teachings of increased tolerance to high light stress with decreased levels of ParG expression. However, Applicant do admit that Panda et al. teach that *Arabidopsis* mutants with decreased ParG expression exhibited a lengthened circadian period that was entirely independent of the frequency or intensity of light to which mutant was exposed (response, paragraph bridging pages 9 and 10).

Applicant's arguments are carefully considered but are deemed to be unpersuasive.

It is maintained that Panda et al. clearly teach that *Arabidopsis tej* mutant having disrupted ParG gene function resulted in lengthened circadian period that was independent of the light quality and quantity. Furthermore, Panda et al. *tej* mutant (disrupted in ParG function) grew normally and set seeds under any light quality and quantity, implying that plants with reduced or disrupted ParG function could grow normally and set seeds under light stress. It may be noted that Panda et al. *tej* mutant which is capable of growing under high light intensity would imply that a plant with ParG disruptive or reduced function is capable of growing normally under high light stress.

Applicant further argues that the combination of Chang et al., Wesley et al. and Panda et al. do not teach each and every element. Applicant continues to argue that Chang et al. SEQ ID NO: 550 is not identical to instant SEQ ID NO: 3. Applicant also continues to argue that Chang et al., Wesley et al. or Panda et al. do not teach that down-regulation of ParG would have resulted in increased tolerance to high light stress (response, page 10, lines 3-25).

Applicant's arguments are carefully considered but are deemed to be unpersuasive.

It may be noted that instant claims are not limited to SEQ ID NO: 3. Rather, claims are also directed to (a) any 163 consecutive nucleotides of instant SEQ ID NO: 3, or (b) nucleotides from positions 973 to 1135 of instant SEQ ID NO: 3. Chang et al. SEQ ID NO: 550 contains both (a) as well as (b) as discussed above. Furthermore, Chang et al. SEQ ID NO: 550 also encodes poly-(ADP-ribose)-glycohydrolase (ParG) protein.

As discussed above, Panda et al. also teach a nucleotide sequence having 100% identity to instant SEQ ID NO: 3, and which encodes poly-(ADP-ribose)-glycohydrolase (ParG) protein which has 100% identity to instant SEQ ID NO: 1. Panda et al. cite GenBank

Accession No. AF394690 (see page 61, last line of right column), wherein the complete nucleotide sequence and its encoded poly-(ADP-ribose)-glycohydrolase (ParG) protein is taught.

It is maintained that Panda et al. clearly establishes the function of ParG in a plant. As discussed above, Panda et al. clearly teach that *Arabidopsis tej* mutant having disrupted PARG gene function resulted in lengthened circadian period that was independent of the light quality and quantity.

It is obvious that one of ordinary skill in the art would have inferred that *tej* mutant could grow under any light quality (same as light frequency) or quantity, thereby implying that *tej* mutant was capable of growing under high light stress.

In response to applicant's argument that cited art does not teach each and every element of the claimed invention, it is important to note that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, one of ordinary skill in the art would have arrived at the claimed invention with a reasonable expectation of success by combing the prior art teachings of Chang et al., Wesley et al. and Panda et al. as discussed above.

Applicant further argues that there is no reason to combine the teachings of Chang et al., Wesley et al. and Panda et al. Applicant argues that Chang et al. teach that the up-regulation or down-regulation of SEQ ID NO: 550 may help improve a plant's ability to survive

pathogenic infections, however, Chang et al. provide no indication that down-regulation of SEQ ID NO: 550 would result in increased tolerance to high light stress, and thus one of skill in the art would not have sought to combine Chang et al. with Wesley et al. and Panda et al. Applicant further argues that even if one of skill in the art had been motivated to consider Panda et al., the reference fails to provide any teaching that the down-regulation of ParG provides increase tolerance to high light stress or even increased resistance to pathogenic infections (response, page 11, lines 1-26).

Applicant's arguments are carefully considered but are deemed to be unpersuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been prima facie obvious, and within the scope of an ordinary skill in the art to modify Chang et al. sense, antisense or cosuppression constructs by designing ParG RNAi (double stranded inhibitory RNA) construct using any method of designing RNAi construct that were well known in the art, including the one taught by Wesley et al. to suppress the endogenous ParG gene expression with a reasonable expectation of success. One of ordinary skill in the art would also have been motivated to employ double stranded RNAi based method of gene silencing because Wesely et al. clearly teach that double-stranded inhibitory RNA is highly efficient (90% to 100% efficiency) method of silencing endogenous plant genes compared to sense, antisense or co-suppression based

methods. It is therefore, maintained that it would have been obvious and within the scope of an ordinary skill in the art to have been motivated in using a double strand RNAi based method of down-regulating the expression of an endogenous plant gene (e.g. ParG in the instant case) as an obvious design choice to arrive at the claimed invention with a reasonable expectation of success.

Given that Panda et al. clearly teach that disrupting ParG gene expression in a plant resulted in the ability of the plant to grow independent of light quality and light intensity as discussed above, it would have been obvious and within the scope of an ordinary skill in the art to inhibit endogenous plant ParG gene expression by transforming a plant with an RNAi inhibitory construct as discussed above to produce transgenic plants that exhibited tolerance to high light intensity stress with a reasonable expectation of success.

Applicant further argues that Panda et al. teach away from the claimed invention. Applicant alleges that page 57 of Panda et al. explains that poly (ADP-ribose) polymerase (PARP) is generally induced in response to cellular stress and PARP catalyzes the poly (ADP-ribosyl)ation of certain proteins, whereas PARG catalyzes the opposite reaction-removing the poly(ADP-ribose) polymers from these tagged proteins. In view of this, Applicant argues that one of skill in the art would not have expected that the down-regulation of ParG, a protein whose activity opposes the activity of PARP, would confer tolerance to high light stress in plants (response, paragraph bridging pages 11 and 12).

Applicant's arguments are carefully considered but are deemed to be unpersuasive.

Applicant's attention is drawn to Panda et al. at page 57 (sentence bridging left and right page), wherein the reference teach that plants disrupted in ParG function exhibited significant accumulation of poly(ADP-ribose) polymers (pADPr polymers). Applicant's

attention is also drawn to page 57 (2nd paragraph of right column), wherein Panda et al. teach that pADPr polymer is produced in response to genotoxic stress (includes high light stress) and plays a critical role in modulating cellular responses to stress.

Given that PARG degrades pADPr polymers produced by poly (ADP-ribose) polymerase (PARP) as asserted by Panda et al. (see page 55, lines 1-5 of 2nd paragraph of right column), it would have been obvious and within the scope of an ordinary skill in the art to have disrupted or down-regulated the expression of endogenous ParG gene for the purpose of increasing tolerance to genotoxic stress (e.g. high light stress) by maintaining higher levels of pADPr polymers. In view of this, Applicant is not on point in arguing that one of skill in the art would not have expected that the down-regulation of ParG, a protein whose activity opposes the activity of PARP, would confer tolerance to high light stress in plants.

It is therefore maintained that the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Conclusions

9. Claims 9, 11-16 remain, and newly added claims 22-24 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory

period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)272-0975. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Vinod Kumar/
Examiner, Art Unit 1638